

NIAMS SMALL GRANT PROGRAM FOR NEW INVESTIGATORS

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PA NUMBER: PAR-99-099

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Application Receipt Dates: June 22, 1999 and October 19, 1999

February 22, 2000, June 21, 2000, and October 18, 2000

February 21, 2001, June 20, 2001, and October 17, 2001

THIS PROGRAM ANNOUNCEMENT (PA) USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking small grant (R03) applications to stimulate and facilitate the entry of promising new investigators into areas of research supported by the NIAMS. Applications are especially encouraged from new investigators who hold a faculty position at an HBCU (Historically Black College or University) or other institutions that have student populations consisting predominantly of individuals from racial or ethnic groups that are underrepresented in science. This solicitation will provide support for pilot research that is likely to lead to a subsequent individual research project grant (R01).

This is a change in our previous policy of one application receipt date each fiscal year for the small grant mechanism. As noted, for calendar year 1999, there will be two application receipt dates, with three receipt dates in 2000 and 2001.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Small Grant Program for the NIAMS, is related to the priority area of chronic diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0 or Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Foreign organizations and institutions are not eligible. Participation in the program by investigators at minority serving institutions is strongly encouraged. Pilot project grants awarded through this PA may not be used to support thesis or dissertation research.

Former and current recipients of NIH small research grants (R03), Academic Research Enhancement Awards (AREA) (R15), Mentored Clinical Scientist Development Awards (K08), Mentored Research Scientist Development Awards (K01), Shannon Awards (R55), or Individual (F32) or Institutional (T32) National Research Service Award (NRSA) training support are eligible to apply for this Small Grant Program, dependent upon the status of other support for the project. Any current support by the F32 or T32 mechanisms must terminate before Small Grant support begins. The work proposed may not overlap significantly with the aims of currently supported projects in which the Principal Investigator has participated during the last five years. (Information on such projects is to be provided as part of the Principal Investigator's Biographical Sketch, as described below under Application Procedures.)

Current and previous recipients of NIH funding through Research Project Grants (R01), FIRST (R29) awards or any non-mentored career development award mechanism are ineligible for this Small Grants Program. Principal Investigators of research subprojects of Research Program Projects (P01) and Centers (P50 and P60) and individuals who have received research support from the National Science Foundation (NSF) or Department of Veterans Affairs (VA) as Principal Investigators are also ineligible. Individuals whose sole previous support has been through pilot and feasibility studies may apply.

Investigators who have questions about eligibility should contact one of the program officials listed under INQUIRIES.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) small grant (R03) mechanism of support. Applicants may request up to \$50,000 (direct costs) per year for up to three years. These awards are not renewable. Before completion of the R03, investigators are encouraged to seek continuing support for research through a research project grant (R01). Replacement of the Principal Investigator on this award is not permitted.

To comply with Grants Policy changes effective June 1, 1999, specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts. The modular grant concept establishes specific modules in which direct costs may be requested under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and institute staff. Complete and detailed instructions and information on Modular Grants can be found at <http://www.nih.gov/grants/funding/modular/modular.htm>.

Applications will request direct costs in \$25,000 modules, up to a total direct cost request of \$50,000 per year. A typical modular grant application will request the same number of modules in each year.

Application budgets will be simplified. Detailed categorical budget information will not be submitted with the application; budget form pages of the application kits will not be used. Instead, total direct costs requested for each year will be presented. Information, in narrative form, will be provided only for Personnel and, when applicable, for Consortium/Contractual Costs. See section on application instructions below.

Additional narrative budget justification will be required in the application only if there is a variation in the number of modules requested.

There will be no routine escalation for future years.

Other Support pages of the PHS 398 will not be submitted with the application.

Information on research projects ongoing or completed during the last three years by the principal investigator and key personnel will be provided as part of the "Biographical Sketch". This information will include the specific aims, overall goals and responsibilities and should include Federal and non-Federal support. This information will be used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project.

Following peer review, information about Other Research Support will be requested by NIH from the applicant for applications being considered for award.

Additional budget information will be requested only under special circumstances.

FUNDS AVAILABLE

It is anticipated that for FY2000 and FY2001, approximately \$1.0 million (total costs) will be available for the first year of support for this initiative. It is anticipated that up to 10 to 15 new grants will be awarded each FY under this program. Awards are contingent on the availability of appropriated funds and on the receipt of sufficiently meritorious applications meeting the stated eligibility requirements.

RESEARCH OBJECTIVES

The NIAMS Small Grant program is designed to facilitate the entry of promising new investigators into areas of research supported by the NIAMS. Appropriate research areas may include, but are not limited to, the following:

- o Vascular manifestations of rheumatic, connective tissue, and skin diseases
- o Studies of vasculitis and vasculopathies in animal models of rheumatic diseases, with emphasis on identification of pathogenetic mechanisms and molecular targets for therapeutic intervention
- o Therapeutic potential of angiogenesis inhibitors/modulators in rheumatoid arthritis, psoriasis, immune and non-immune inflammation of the skin (including irritant and allergic contact dermatitis), autoimmune diseases of skin, atopic dermatitis, and wound healing

- o Mechanisms of self-recognition in autoimmunity and design of therapies to prevent abnormal responses to self by affecting antigen processing
- o Mechanisms of end organ damage in rheumatic and skin disease and dissection of the genetics of end-organ disease
- o Primary and secondary analysis of data sets from arthritis and musculoskeletal and skin disease studies (clinical trials, epidemiology or applied)
- o Stem cell biology as related to skin, cartilage, bone, and muscle
- o Growth and repair of connective tissues, including skin, bone, cartilage, tendon, ligament, muscle, and the intervertebral disc
- o Interactions between matrices/scaffolds and cells in the use of tissue engineering to repair bone, connective tissues, and skin
- o Mechanisms of bone, cartilage, muscle, and connective tissue responses to mechanical loading
- o Molecular mechanisms underlying the responses of muscle to physical activity
- o Interactions of bone and connective tissue with materials of orthopedic instruments, implants and prostheses, the enhancement of integration with bone, and the development of optimal designs and materials to facilitate this tissue biomaterial interaction
- o Response of connective tissue to repetitive stresses, including healing/repair, a better understanding of the relationship at the biological and biomechanical interface, and the development and validation of suitable animal models
- o Models and markers of gender and genetic factors in musculoskeletal injuries and diseases, including animal models of human disease
- o Studies of regulation of cell signaling in autoreactive cells in lupus, rheumatoid arthritis and other rheumatic diseases
- o Mechanisms underlying the relationship between the female gender and increased susceptibility to rheumatic diseases

- o Rheumatic, muscular, and dermatological manifestations of acquired immunodeficiency syndrome
- o Pathogenesis of alopecia areata and vitiligo
- o Pathogenesis, genetics, biochemistry, molecular and cellular biology of keloids
- o Pathogenesis of genetic muscle diseases.

This list is intended to be illustrative and not exclusive or restrictive. The purpose of this PA is to promote investigator initiated research projects on arthritis and musculoskeletal and skin diseases and injuries.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994. This information is available on the internet at <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that children must be included in all human subjects research conducted or supported by the NIH unless there are scientific or ethical reasons not to include them. The

goal of the policy is to increase the participation of children in research to obtain appropriate data. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts, March 6, 1998. This information is available on the internet at <http://www.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators also may obtain copies of the policies on "Inclusion of Women and Minorities in Research Involving Human Subjects" and "Inclusion of Children as Participants in Research Involving Human Subjects" from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the research grant application form PHS 398 (rev. 4/98), with the modifications noted below. For this program announcement, application receipt dates are June 22, 1999, October 19, 1999, February 22, 2000, June 21, 2000, October 18, 2000, February 21, 2001, June 20, 2001 and October 17, 2001. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, Email: grantsinfo@nih.gov; and on the internet at <http://www.nih.gov/grants/funding/phs398/phs398.html>.

The PA title, NIAMS Small Grant Program for New Investigators, and number (PAR-99-099) must be typed on line 2 of the face page of the application form and the YES box must be checked.

BUDGET INSTRUCTIONS

The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

- o FACE PAGE - Items 7a and 7b should be completed, indicating Direct Costs (in

\$25,000 increments up to a maximum of \$50,000) and Total Costs [Modular Total direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

- o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

- o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form page 5 of the PHS 398. It is not required and will not be accepted with the application.

- o NARRATIVE BUDGET JUSTIFICATION - Use a Modular Grant Budget Narrative page.

(See <http://www.nih.gov/grants/funding/modular/modular.htm> for sample pages.)

At the top of the page, enter the total direct costs requested for each year.

- o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount.

Provide an additional narrative budget justification for any variation in the number of modules requested.

- o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at:

<http://www.nih.gov/grants/funding/modular/modular.htm>.

- Complete the educational block at the top of the form page;
- List current position(s) and then previous positions;

- List selected peer-reviewed publications, with full citations;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed in the last three years.

o CHECKLIST - This page should be completed and submitted with the application.

If the F&A rate agreement has been established, indicate the type of agreement and the date. It is important to identify all exclusions that were used in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

o Description of the Research Plan is limited to 10 pages.

APPLICATIONS NOT CONFORMING TO THESE GUIDELINES WILL BE CONSIDERED UNRESPONSIVE TO THIS PA AND WILL BE RETURNED WITHOUT FURTHER CONSIDERATION.

Submit a signed typewritten original of the application and three signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC-7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, one additional copy of the application must be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U - MSC 6500
Bethesda, MD 20892-6500

In order not to delay review, it is important that applicants comply with this request.

Applications received after any of the receipt dates listed above will be deferred to the next review cycle. A Principal Investigator may submit only one Small Grant application to the NIAMS in any review cycle. Applicants may not submit an application for the same review cycle in which a Small Grant is submitted, if that application involves significant scientific overlap with the Small Grant application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR. Incomplete applications will be returned to the applicant without further consideration. NIAMS staff will review applications for responsiveness to the research objectives of this PA and for the eligibility of the Principal Investigator under the requirements stated above. Applications found to be unresponsive or ineligible will be returned without further consideration. Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review committee convened by the NIAMS in accordance with the usual NIH peer review procedures.

Review Criteria

Review criteria and major factors to be considered in the evaluation of the applications will include:

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in the assignment of the overall score.

(1) Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics?

(3) Innovation. Does the project employ novel concepts, approaches or method?

Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address the adequacy of plans to include both genders and minorities and their subgroups, and children as appropriate for the scientific goals of the research, or justification for exclusion. will be reviewed. If applicable, plans for the recruitment and retention of subjects will also be evaluated.

The personnel category will be reviewed for appropriate staffing based on the requested percent effort. The direct costs budget request will be reviewed for consistency with the proposed methods and specific aims. Any budgetary adjustments recommended by the reviewers will be in \$25,000 modules. The duration of support will be reviewed to determine if it is appropriate to ensure successful completion of the requested scope of the project.

AWARD CRITERIA

The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Importance of the area to NIAMS research
- o Availability of funds.

INQUIRIES

Inquiries concerning this PA are encouraged. Additional information, including sample budget narratives and biographical sketch, may be found at:

<http://www.nih.gov/grants/funding/modular/modular.htm>. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to one of the following persons, according to scientific area:

Orthopedics and Bioengineering

Dr. James S. Panagis
45 Center Drive, Room 5AS-37K
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 594-4543
Email: jp149d@nih.gov

Rheumatic Diseases

Dr. Susana A. Serrate-Sztein
45 Center Drive, Room 5AS-37G
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: SzteinS@ep.niams.nih.gov

Cartilage and Connective Tissue

Dr. Bernadette Tyree
45 Center Drive, Room 5AS-37J
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 594-4543
Email: TyreeB@ep.niams.nih.gov

Muscle Biology

Dr. Richard W. Lymn
45 Center Drive, Room 5AS-49E

Bethesda, MD 20892-6500
Telephone: (301) 594-5128
FAX: (301) 480-4543
Email: LymnR@ep.niams.nih.gov

Skin Diseases

Dr. Alan N. Moshell
45 Center Drive, Room 5AS-25L
Bethesda, MD 20892-6500
Telephone: (301) 594-5017
FAX: (301) 480-4543
Email: alan_n_moshell@nih.gov

Bone Biology

Dr. William J. Sharrock
45 Center Drive, Room 5AS-37A
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: SharrocW@ep.niams.nih.gov

Bone Diseases

Dr. Joan McGowan
45 Center Drive, Room 5AS-43E
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: McgowanJ@ep.niams.nih.gov

Direct inquiries regarding fiscal matters to:

Sally A Nichols
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin

Diseases

45 Center Drive, Room 5AS-49F, MSC 6500

Bethesda, MD 20892-6500

Telephone: (301) 594-3535

FAX: (301) 480-5450

Email: NicholsS@ep.niams.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke free workplace and promote the non-use of all tobacco products. In addition, Public law 103-227, the pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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